PATENT
Application No. 09/868,379
Filing Date: 08/15/2001
Examiner: Frederick F. Krass
Art Unit: 1614
Attorney Docket No. H03763/219-06

EXHIBIT A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the United States Patent Application of :
Applicants: Christian Kropf,
Ulrike Brüninghaus,
Amerigo Pastura,
Michael Meinders,
Peter Wülknitz,
Rolf Hempelmann and
Marcel Roth

Application Serial No. 09/868,379
Filing Date: 08/15/2001
Claiming priority of International Application
PCT/EP99/09683, filed 12/09/1999
and German Application
DE 198 53 662.0, filed 12/18/1998

Examiner: Frederick F. Krass
Art Unit: 1614

Assignee: Henkel KGaA

Title: **FINE SUSPENSIONS OF POORLY SOLUBLE CALCIUM SALTS AND THEIR USE IN DENTAL CARE PRODUCTS**

SECOND DECLARATION OF CHRISTIAN KROPF

I, Christian Kropf declare as follows:

1. I am an inventor of United States Patent Application No. 09/868,379.

2. I am head of a department in Corporate Research Chemistry at Henkel KGaA, Henkelstraße 67, 40589 Düsseldorf, Germany. I obtained both a diploma degree in Chemistry in 1992 and a Ph.D. degree in Engineering Sciences (new materials) in 1998 from Saarland University in Saarbruecken, Germany.

3. I am familiar with United States Patent Application No. 09/868,379 of Christian Kropf et al. (hereinafter the "Kropf application"), United States Patent No. 6,919,070 to Rudin et al. and an English language translation of Japanese Patent Document 6-329557 to Oda et al. that was included with an United States Patent and Trademark Office Examiner's Action dated April 23, 2007, on the Kropf application.

4. Claim 8 of the Kropf application is directed to a suspension. The remaining claims 9–10, 13–17 and 20–21 are directed to a toothpaste comprising the suspension, a method of remineralizing teeth comprising the suspension, or other suspensions within the scope of claim 8. Claim 8 reads as follows:

> Claim 8. A suspension of one or more phosphate calcium salts, fluoride calcium salts, or flurophosphate calcium salts in a liquid medium in which the salts are less than 1 g/l soluble, wherein the calcium salts comprise primary particles having diameters of from 5 to 50 nanometers and lengths of from 10 to 150 nanometers, stabilized against agglomeration by a content of at least 0.01% by weight, based on the weight of the suspension, of a water-soluble surfactant or of a water-soluble polymeric protective colloid selected from the group consisting of gelatin, casein, starch, plant gums, cellulose ethers, methylcellulose, hydroxyethylcellulose, carboxymethylcellulose, hydroxyethylstarch and hydroxypropyl guar, adsorbed onto said particles

5. The Rudin et al. patent discloses a composition characterized in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d), and thickness (h). The values for these dimensions are: (l) from 0.2 μm to 0.01 μm, (d) 0.1 μm to about 0.001 μm and (h) from 0.1 μm to 0.0001 μm (column 2, lines 22–27).

6. Rudin et al. further discloses that the hydroxyapatite being introduced into the composition possesses osteo-reparative properties and contains preferably about 100% $Ca_{10}(PO_4)_6(OH)_2$ and that the specific surface of hydroxyapatite used in the composite advantageously is 100 to 150 m^2/g (column 2, lines 41-45). This disclosure indicates that the hydroxyapatite disclosed in Rudin et al. is pure hydroxyapatite.

7. Rudin et al. further discloses an oral product that will comprise a liquid phase containing humectants and binding thickeners which act to maintain the particulate solid abrasive and hydroxyapatite crystals in the form of stable suspension in liquid phase (Column 3, lines 11-15). On the basis of the disclosure in Rudin et al. identified in Paragraph 6 of my Declaration, the hydroxyapatite crystals in the suspension are pure hydroxyapatite.

8. My conclusion that the hydroxyapatite particles disclosed in Rudin et al. are pure is further based on the disclosure at column 2, lines 46-51 of Rudin et al. that U.S. Patent No. 6,254,855 B1 describes a method for producing a suspension of hydroxyapatite as described in the Rudin et al. application. U.S. Patent No. 6,254,855 B1 discloses in Example 1 that according to the method described in that patent, a pure stochiometric hydroxylapatite in a suspension form is produced free of admixtures (Column 3, lines 43-67).

9. The calcium particles claimed in Claim 8 of the Kropf application are not pure hydroxyapatite. They are particles of calcium salt with a water-soluble surfactant or colloid selected from a group of water-soluble polymeric protective colloids adsorbed onto said particles. Accordingly, the particles claimed in the Kropf application are different in composition than the pure hydroxyapatite particles disclosed in Rudin et al.

10. A comparison of the suspension claimed in Claim 8 with the suspension disclosed in Rudin et al. reveals that the claimed suspension is distinct from the suspension taught or suggested by Rudin et al. Rudin et al. discloses crystals of pure hydroxyapatite of a defined particle size that are maintained in a suspension. Applicants' claimed suspension is of particles of calcium salts, wherein a water-soluble surfactant or defined water-soluble polymeric protective colloid is adsorbed onto said particles. Accordingly, Rudin et al. does not disclose or suggest Applicants' claimed suspension comprising particles of one or more calcium salts with a colloid adsorbed onto said particles, which is set forth in all of Applicants' pending claims 8–10, 13–17, 20 and 21.

11. Oda et al. relates to a carrier for absorbing a biologically active substance and medicinal preparation in which a biologically active substance is absorbed by this carrier (Paragraph [0001]). The Oda et al. invention is directed to a carrier for absorbing a biologically active substance comprising fine particles of hydroxyapatite with an average particle diameter of 500 nm or less surface-processed with albumin and/or a polyhydric organic acid (Paragraph [0006])

12. In Working Example 1 of Oda et al., fine particles of hydroxyapatite are surface treated with human serum albumin and low molecular weight gelatin in concentrations of 0.5 mg/ml, 1.5 mg/ml and 4.5 mg/ml (all aqueous solutions) (Paragraph [0017]). The dispersion of the surface-treated hydroxyapatite fine particles was measured using a granularity distribution measuring device (Shimazu Works) and the average particle diameter was determined. The effect of the human serum albumin and low molecular weight gelatin on the dispersion is shown in Table 1 on page 8 of the English text (Paragraphs [0018]–[0019]).

13. Oda et al. then discloses that according to the data set forth in Table 1, it is clear that the average particle diameter of the particles with human serum albumin was 100 nm or less, and that there was no aggregation and good dispersion properties no matter how much was added. When the low molecular weight gelatin was added, aggregation occurred and approximately 80% had an average particle diameter of 500 nm or more no matter how much was added.

14. The result disclosed in Oda et al. teaches away from Applicants' claimed suspension of particles "stabilized against agglomeration by a content of at least 0.01% by weight, based on the weight of the suspension, of a water-soluble surfactant or of a water-soluble polymeric protective colloid selected from the group consisting of gelatin, casein, starch, plant gums, cellulose ethers, methylcellulose, hydroxyethylcellulose, carboxymethylcellulose, hydroxyethylstarch and hydroxypropyl guar, adsorbed onto said particles. In other words, Applicants' claimed suspension may include gelatin but does not include albumin or a polyhydric organic acid. In contrast, one of ordinary skill in the art of the subject matter of Applicants' invention relying on the teaching in Oda et al. that "when gelatin was added, aggregation occurred and approximately 80% had an average particle diameter of 500 nm or more no matter how much was added" would conclude that gelatin is unsuitable for stabilizing particles of hydroxyapatite against agglomeration. Accordingly, one of ordinary skill in the art could not derive Applicants' claimed suspension of particles from Oda et al.

15. For the reasons set forth above, the Rudin et al. and the Oda et al. suspensions of particles are distinct from Applicants' claimed suspension of particles of calcium salt wherein a water-soluble surfactant or water-soluble polymeric protective colloid, as defined in Applicants' Claim 8, is adsorbed onto said particles. Indeed, Oda et al. teaches away from attempting to adsorb gelatin onto the Oda et al. particles. Accordingly, Oda et al., like Rudin et al., does not disclose or suggest Applicants' claimed suspension comprising particles of calcium salt with the surfactant or colloid as defined in Claim 8 adsorbed onto said particles, which is set forth in all of Applicants' pending claims, 8-10, 13-17, 20 and 21.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 19 of the United States Code, and that such willful false statements may jeopardize the validity of the Kropf application or any patent issued thereon.

Dated: August 22, 2007

CHRISTIAN KROPF